

Lack of novelty

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Amendments to the Claims:

Please cancel claims 1-17 without prejudice or disclaimer of the subject matter contained therein.

18. (New) A spore genetically modified with genetic code comprising at least one
2 genetic construct encoding an antigen and a spore coat protein as a chimeric gene, said
genetically modified spore having said antigen expressed as a fusion protein with said spore coat
4 protein for use in oral or intranasal or rectal administration for therapeutic treatment.

19. (New) A spore as claimed in claim 18, wherein the spore is of *Bacillus* species.

20. (New) A spore as claimed in claim 18, wherein the genetic construct comprises at
2 least part of a spore coat protein gene and at least part of an antigen gene, in the form of a
chimeric gene.

21. (New) A spore as claimed in claim 18, wherein the antigen gene is located at the
2 3' end of the spore coat protein gene.

22. (New) A spore as claimed in claim 18, wherein the genetic construct comprises a
2 spore coat promoter at the 5' end of the chimeric gene.

23. (New) A spore as claimed in claim 22, wherein the antigen is at least one of
2 tetanus toxin fragment C or labile toxin B subunit.

[1-17] *

24. (New) A spore as claimed in claim 18, wherein the spore coat protein is selected
2 from the group consisting of *cotA*, *cotB*, *cotC*, *cotD*, *cotE*, *cotF*, *cotG*, *cotH*, *cotJA*, *cotJC*, *cotM*,
cotSA, *cotS*, *cotT*, *cotV*, *cotW*, *cotX*, *cotY* and *cotZ*.

25. (New) A spore as claimed in claim 24, wherein the spore is heat inactivated so
2 that in use it does not germinate into a vegetative cell.

26. (New) A spore as defined in claim 18 for use in the treatment of a medical
2 condition.

27. (New) A composition comprising at least two different spores as defined
2 in claim 18, wherein said at least two different spores express at least two different
antigens.

28. (New) A composition as defined in claim 27, wherein the composition
2 further comprises a pharmaceutically acceptable excipient or carrier.

29. (New) A composition comprising a spore as defined in claim 18 in
2 association with a pharmaceutically acceptable excipient or carrier for use in oral or
intranasal or rectal administration for therapeutic treatment.

30. (New) A composition comprising a spore as defined in claim 26 in
2 association with a pharmaceutically acceptable excipient or carrier for use in oral or
intranasal or rectal administration for therapeutic treatment.

31. (New) A composition as defined in claims 27, 28 or 29, for use in
2 treatment of a medical condition, preferably the medical condition is inflammation,
pain, a hormonal imbalance and/or an intestinal disorder.

32. (New) Use of a spore as defined in claim 18 in the manufacture of a
2 medicament for use in the treatment of a medical condition, preferably the medical
condition is inflammation, pain, a hormonal imbalance and/or an intestinal disorder.

33. (New) Use of a spore as defined in claim 26 in the manufacture of a
2 medicament for use in the treatment of a medical condition, preferably the medical
condition is inflammation, pain, a hormonal imbalance and/or an intestinal disorder.

34. (New) A method of medical treatment, which method comprises the steps
2 of
a) administering a spore as defined in claim 18 to a human or animal in need
4 of medical treatment by an oral, intra-nasal or rectal route;
b) said genetically modified spore eliciting an immune response for use in
6 the prevention of a disease.

35. (New) A method of medical treatment, which method comprises the steps
2 of

- a) administering a spore as defined in claim 26 to a human or animal in need
4 of medical treatment by an oral, intra-nasal or rectal route;
- b) said genetically modified spore eliciting an immune response for use in
6 the prevention of a disease.

36. (New) A method of producing a genetically modified spore, which method
2 comprises the steps;

- producing genetic code comprising at least one genetic construct encoding an antigen and
4 a spore coat protein as a chimeric gene;
- using said at least one genetic construct to transform a vegetative mother cell;
6 inducing said transformed mother cell to sporulate; and
- isolating the resulting genetically modified spores.